REMARKS

Summary of the Office Action

Claims 21-26, 31-33, and 37-40 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by U.S. Patent No. 5,545,178 to Kensey et al. ("*Kensey*").

Claims 34-35 have been rejected under 35 U.S.C. 103(a) as allegedly obvious over *Kensey* in view of U.S. Patent No. 6,391,037 to Greenhalgh ("*Greenhalgh*").

Claim 36 has been rejected under 35 U.S.C. 103(a) as allegedly obvious over *Kensey* in view of U.S. Patent No. 5,649,959 to Hannam et al. ("*Hannam*")

Response to the Office Action

Claims 21-40 are pending in the application. In the present amendment, claims 21, 22, and 26 have been amended, and claims 27-30 (previously withdrawn from consideration) have been canceled. Therefore, upon entry of the present amendment, claims 21-26 and 31-40 will be subject to examination.

A. The Rejections under 35 U.S.C. 102(b)

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See also MPEP 2131.

The rejection of claims 21-26, 31-33, and 37-40 as allegedly anticipated by *Kensey* is respectfully traversed, because it is believed that *Kensey* does not teach each and every element of Applicant's claimed invention.

With specific regard to independent claim 21, *Kensey* does not teach, among other things:

1. the inner tube further having a plurality of lateral openings in fluid communication with the outer tube;

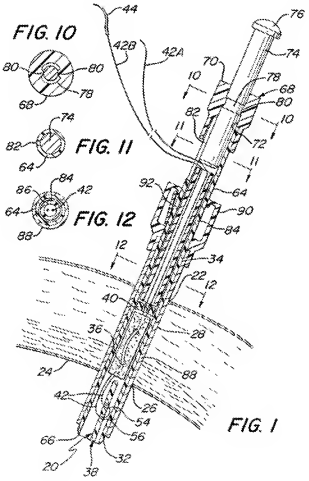
2. a volume of blood provided in the lumen of the inner tube being mixable with a blood congealing agent provided to the volume of blood to form the autologous plug;

3. formation of the autologous plug from the volume of blood by action of the blood congealing agent.

As best understood, *Kensey* discloses a system and a method for sealing a percutaneous

puncture in a living vessel and in the neighboring tissue by using a trocar that inserts an anchoring member into the vessel and that also inserts an optional sealing member into the neighboring tissue. The anchoring member and the sealing member are eventually stitched into the tissue. The sealing member in *Kensey* "basically comprises a strip of a compressible, resorbable, collagen foam … [which] includes a thin web or strip of a non-resorbale, e.g. dacron, reinforcing mesh **46** embedded within it." *Kensey*, Col. 8, lines 25-29.

More particularly, *Kensey* does not teach that the inner tube has "lateral openings," because the inner tube of *Kensey* is open only at the longitudinal ends (see, e.g., FIG. 1 of *Kensey*, reproduced below).



Further, *Kensey* does not teach a device configured to provide a volume of blood "in the lumen of the inner tube," because *Kensey* prevents flow of blood into the lumen of the inner tube by inserting holding member 40 between sealing member 36 and the inner tube.

Still further, *Kensey* does not provide "a blood congealing agent" to form "the autologous

plug." The American Heritage Dictionary of the English Language, 4th ed. (2000) defines "congeal" as "to cause to solidify or coagulate or to undergo a process likened to solidification or coagulation," and defines "autologous" as "derived or transferred from the same individual's body."

Contrary to that, *Kensey* teaches at col. 11, lines 22-33 (cited by the Examiner):

> As will be appreciated by those skilled in the art since the sealing member is formed of compressed collagen (or other hydrolytic material) it expands automatically in the presence of blood or body fluids within the puncture tract when deployed, thereby further contributing to its deformation, e.g., enlargement, within the puncture tract. In addition the expansion/deformation of the sealing member serves to aid in securing the device 20 in place. Thus, it is contemplated that in some applications the deformation/expansion of the sealing means will serve as the only or primary means for securing the device in place within the puncture.

Therefore, sealing member 30 does not cause a volume of blood to congeal, because it is sealing member 30 that expands due to the presence of blood while the blood remains in a fluid state. Further, sealing member 30 is not an autologous plug, because it is not derived or transferred from the patient's body but instead is made of a foreign substance such as compressed collagen.

At least for the foregoing reasons, claim 21 is not anticipated by *Kensey*. Claims 22-26, 31-33, and 37-40 are not anticipated by *Kensey* for the same reasons as claim 21 and for the additional limitations contained therein.

B. The 35 U.S.C 103(a) Rejections

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). See also MPEP 2143.03

Applicant submits that claims 34 and 35 are not obvious in view of *Kensey* and *Greenhalgh*, because *Kensey* does not teach all the limitations of claims 34 and 35 and because *Greenhalgh* fails to correct the deficiencies of *Kensey*.

Kensey has been discussed in the preceding section. *Greenhalgh* has been cited by the Examiner for disclosing a platinum and thermo-resistive wire. Based on the Examiner's citation and on the other disclosures of *Greenhalgh*, it is believed that *Greenhalgh* does not teach the missing elements of *Kensey*, such as the inner tube further having a plurality of lateral openings

in fluid communication with the outer tube, a volume of blood provided in the lumen of the inner tube being mixable with a blood congealing agent provided to the volume of blood to form the autologous plug, and formation of the autologous plug from the volume of blood by action of the blood congealing agent.

Applicant also submits that claim 36 is not obvious in view of *Kensey* and *Hannam*, because *Kensey* does not teach all the limitations of claim 36 and because *Hannam* fails to correct the deficiencies of *Kensey*.

Kensey has been discussed in the preceding section. *Hannam* has been cited by the Examiner for disclosing the use of fibrin and trombin to promote hemostastasis. Based on the Examiner's citation and on the other disclosures of *Hannam*, it is believed that *Hannam* does not teach the missing elements of *Kensey*, such as the inner tube further having a plurality of lateral openings in fluid communication with the outer tube, a volume of blood provided in the lumen of the inner tube being mixable with a blood congealing agent provided to the volume of blood to form the autologous plug, and formation of the autologous plug from the volume of blood by action of the blood congealing agent.

Conclusion

Applicant believes that all objections and rejections raised by the Examiner have been fully addressed and that the present application is in condition for allowance. A notice to that effect is respectfully requested.

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Respectfully submitted,

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